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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,268

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Keiji Kubo

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EXAMINER

TUCKER, ZACHARY C

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

04/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,268	Applicant(s) KUBO ET AL.	
	Examiner Zachary C. Tucker	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 33-37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-29 and 33-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>19Sep06, 27Nov06</u> . | 6) <input type="checkbox"/> Other: ____. |

***Lack of Unity of Invention
~and~
Requirement for Election of Species***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 3-7, 9-19, 21-25, 27-29 and 33-37 (all in part), drawn to compounds represented by the formula (I), wherein ring A represents a pyrrolidine ring, a pharmaceutical preparation comprised thereof, and methods of treatment comprising administering an effective amount of such compounds.

Group II, claims 1, 3-7 (1 and 3-7 in part), claim 8, claims 9-19 (claims 9-19 in part), claim 20, claims 21-25, 27-29 and 33-37 (claims 21-25, 27-29 and 33-37 in part), drawn to compounds represented by formula (I), wherein ring A represents a piperidine ring, a pharmaceutical preparation comprised thereof, and methods of treatment comprising administering an effective amount of such compounds.

Group III, claims 1, 3-7, 9-19, 21-25, 27-29 and 33-37 (all in part), drawn to compounds represented by the formula (I), wherein ring A represents a perhydroazepine ring, a pharmaceutical preparation comprised thereof, and methods of treatment comprising administering an effective amount of such compounds.

Group IV, claim 2 (in part), drawn to a prodrug of a compound as set forth in Group I hereinabove.

Group V, claim 2 (in part), drawn to a prodrug of a compound as set forth in Group II hereinabove.

Group VI, claim 2 (in part), drawn to a prodrug of a compound as set forth in Group III hereinabove.

Group VII, claim 26 (in part), drawn to a process for preparing a compound as set forth in Group I hereinabove.

Group VIII, claim 26 (in part), drawn to a process for preparing a compound as set forth in Group II hereinabove.

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Group IX, claim 26 (in part), drawn to a process for preparing a compound as set forth in Group III hereinabove.

The inventions listed as Groups I to V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The three different identities for ring "A" set forth in instant claim 1 provide for the finding of lack of Unity of Invention under the PCT rules, as those three different identities for "A" are non-overlapping and do not share a common structural feature.

Prodrugs of formula (I) compounds, furthermore, do not fall within the scope of formula (I), as a prodrug must be converted to a formula (I) compound *in vivo*, upon metabolism in some organism.

This Requirement Is Further Set Forth as Follows:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicant is also required, therefore, in reply to this action, to elect a single disclosed species of (for Groups I-III and VII-IX) formula (I), or a single disclosed species of the prodrug of formula (I) compounds (for Groups IV-VI), to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all

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the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The ring "B" in formula (I) is generic to a plurality of different species, including polycyclic imidazole-containing moieties, and different configurations of (monocyclic)imidazole moieties. Also, variables W, Y, Z¹ and Z³ represent a bond or a divalent group, providing for non-overlapping species variants which do not share a common special technical feature.

This Requirement Is Subject to the Following Conditions:

The examiner has required restriction between claims drawn to compounds and claims drawn to a method for their preparation. Where applicant elects claims directed to compounds, and a compound claim is subsequently found allowable, withdrawn claims drawn to a method for the preparation of the allowable compounds, that depend from or otherwise include all the limitations of the allowable compound claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method for preparation claims that depend from or otherwise include all the limitations of the patentable compound will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the compound claims and the rejoined method for preparation claims will be withdrawn, and the rejoined method for preparation claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected compound claim is found allowable, an otherwise proper restriction requirement between compound claims and method for preparation claims may be maintained. Withdrawn method for preparation claims that are not commensurate in scope with an allowed compound claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the method for preparation claims should be amended during prosecution either to maintain dependency on the compound claims or to

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otherwise include the limitations of the compound claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Monday to Friday from 9:00am to 5:00pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

/Zachary C. Tucker/
Primary Examiner
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